

New set of claims (21 July 2004)

CLAIMS

1. A vessel for dissolution testing of a pharmaceutical delivery device, comprising:
an inert vessel wall and an inert vessel bottom such that the vessel is able to hold a fluid medium;
an inert retainer provided by or at the vessel wall or vessel bottom, for holding an annular pharmaceutical delivery device; and which retainer allows a passageway to the vessel bottom for a sampling tube.
2. A vessel according to claim 1, wherein the vessel wall and vessel bottom together form one transparent glass entity.
3. A vessel according to claim 1 or 2, wherein the retainer comprises an annular plate, which annular plate comprises a passageway for a sampling tube in the middle, and which annular plate is placed inside the vessel at the vessel wall.
4. A vessel according to claim 1 or 2, wherein the retainer is permanently fixed to the vessel wall or vessel bottom.
5. A vessel according to claim 1 or 2, wherein the retainer comprises one or more annular ledges or rims; or one or more bulges; and wherein the annular ledges or rims or the bulges are protruding inwardly from the vessel wall or vessel bottom.

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6. A vessel according to claim 1 or 2, wherein the retainer comprises two sets of bulges formed by indentation of the vessel wall or vessel bottom.

7. A vessel according to claim 1 or 2, comprising a retainer provided by or at the vessel wall or vessel bottom, with which retainer a flexible annular pharmaceutical delivery device can be held.

8. A vessel according to claim 8, wherein the flexible annular pharmaceutical delivery device comprises at least one compartment which comprises a thermoplastic polymer core and a thermoplastic polymer skin covering the core, which core comprises a mixture of a progestogenic compound and an estrogenic compound, and which skin is permeable for the progestogenic and estrogenic compounds.

9. A method for preparing a vessel according to anyone of claims 4 to 6 comprising melting or gluing a retainer to the vessel wall or vessel bottom or by applying one or more indentations to the vessel wall or vessel bottom.

10. A method for dissolution testing of a pharmaceutical delivery device, which delivery device contains a pharmaceutically and/or contraceptive effective amount of drug, comprising:

placing a fluid medium and stirring means in a dissolution vessel according to anyone of claims 1-9;

placing a pharmaceutical delivery device in the retainer of the dissolution vessel according to anyone of claims 1-9;

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rotating the stirring means to circulate the fluid medium in the dissolution vessel; and
sampling one or more predetermined volumes of the fluid medium at selected time intervals by means of a sampling tube.

11. An apparatus for dissolution testing of a pharmaceutical delivery device, comprising:

one or more dissolution vessels according to anyone of claims 1-9 which dissolution vessels are suitable for holding a fluid medium;

one or more stirring means;

a sampling and/or discharging device with one or more sampling and/or discharging tubes suitable for sampling and/or discharging one or more predetermined volume fractions of the fluid medium from the dissolution vessels; and

optionally, a refilling device suitable for adding fluid medium to the dissolution vessels.